#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

### **Before the Board of Patent Appeals and Interferences**

### In re the Application of

Inventors : Eric Jonsen

Application No. : 10/574,342 From PCT/IB2004/051705

Filed : March 30, 2006

For : APPARATUS AND METHOD FOR PACKAGING

AN ELECTRODE

#### APPEAL BRIEF

On Appeal from Group Art Unit 3766

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#### I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded March 30, 2006 at reel 017773, frame 0620.

#### II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

#### III. STATUS OF CLAIMS

Claims 2-16 are pending in the application and stand finally rejected. Claim 1 has been canceled. The claims being appealed are Claims 2-16.

#### IV. STATUS OF AMENDMENTS

An amendment under 37 CFR §1.116 was filed in response to the final Office action mailed July 16, 2007. This amendment was entered for purposes of this appeal by an Advisory Action mailed October 30, 2007.

#### V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention as per Claims 2 and 3 and their dependent claims is an enclosure for a defibrillator electrode 12, shown in Fig. 1, which seals the electrode against moisture loss while the electrode remains in electrical communication with a defibrillator 200 (Fig. 2), comprising an enclosure (shown in Fig. 5 and described on page 5 of the specification) formed of flexible material 32 which is adapted to be sealed against moisture loss as shown in Fig. 3 and

describe on page 3, line 31 to page 4, line 9 of the specification; an interior connector 28,30 located on the interior of the enclosure as shown in Fig. 3 and adapted to detachably connect to a defibrillator electrode as described on page 4, lines 10-12; and an exterior connector 29,31 located on the outside 19 of the enclosure as shown in Fig. 5 and adapted to detachably connect to a defibrillator 20 as described on page 4, lines 12-15, the exterior connector being in electrical communication with the interior connector as shown in Fig. 4, and further comprising a defibrillator electrode 12 having a wireset 14 detachably coupled to the interior connector 28 as described on page 4, lines 10-12, wherein the defibrillator electrode is sealed inside of the enclosure as by sealing surface 22 described on page 4, lines 19-26 and sealing zone 38 shown in Fig. 5. In the embodiment of Claim 3, a defibrillator 200 is coupled to the exterior connector 29,31.

Claim 14 describes a method for packaging a defibrillator electrode 12 comprising providing a sealable flexible enclosure having an interior connector 27,28,30 in the inside 34 of the enclosure as shown in Fig. 3 and an exterior connector 19.29,31 on the outside of the enclosure as shown in Fig. 5, the interior and exterior connectors being in electrical communication with each other as shown in Fig. 4 and described on page 5, lines 18-26; disposing a defibrillator electrode 12 in the interior of the enclosure as described on page 5, lines 24-26, the electrode having an adapter 16 in electrical communication with the interior connector 27,28,30; sealing the enclosure to retard moisture loss as described on page 5, lines 24-26; and connecting the exterior connector 19,29,31 to be in electrical communication with a defibrillator as described on page 5, lines 28-33.

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## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether Claims 2-4, and 9-14 were correctly rejected under 35 U.S.C. §102(b) as anticipated by international publication WO03/037176 (Solosko et al.) and whether Claims 5-8, and 15-16 were rejected under 35 U.S.C. §103(a) as unpatentable over Solosko et al. in view of US Pat. 5,462,157 (Freeman et al.)

#### VII. ARGUMENT

# A. Rejection of Claims 2-4 and 9-14 as anticipated by international publication WO03/037176 (Solosko et al.)

Claim 2 describes an enclosure for a defibrillator electrode which seals the electrode against moisture loss while the electrode remains in electrical communication with a defibrillator, comprising an enclosure formed of flexible material which is adapted to be sealed against moisture loss; an interior connector located on the interior of the enclosure and adapted to detachably connect to a defibrillator electrode; and an exterior connector located on the outside of the enclosure and adapted to detachably connect to a defibrillator, the exterior connector being in electrical communication with the interior connector, and further comprising a defibrillator electrode having a wireset detachably coupled to the interior connector, wherein the defibrillator electrode is sealed inside of the enclosure. In the embodiment of Claim 2, a defibrillator electrode and its wireset are detachably coupled to an interior connector and are in communication with an exterior connector which is adapted to be detachably connected to a defibrillator. This arrangement means that the entire electrode including its wireset can be tested by the defibrillator for moisture loss while sealed in the enclosure. The exterior connector can be

disconnected from the defibrillator and the defibrillator connected to a new sealed

electrode if the present one has become desiccated. The enclosure can be opened and

the electrode applied directly to a patient for rescue without changing any of the

connections; the packaged electrode is pre-connected to the defibrillator and

immediately ready for use. If an emergency medical response person arrives and

wants to connect the patient-applied electrodes to his or her ALS

defibrillator/monitor, the electrode wireset can be disconnected from the interior

connector and connected directly to the ALS defibrillator/monitor for further

monitoring of the patient's condition. Another possibility is to disconnect the

electrode from the interior connector and connect the electrode directly to the original

defibrillator. The enclosure with its connectors can then be disposed of in either

instance.

Claim 3 is similar and also recites that the exterior electrode is coupled to a

defibrillator.

The Solosko et al. publication is of another application of the assignee of the

present application. The benefits described immediately above are not possible with

the Solosko et al. arrangement. The Examiner cites the package 33 of Fig. 8 of

Solosko et al. as anticipating the present invention. This is not the case, however, as

Solosko et al. do not have an interior connector as recited in the Claims 2 and 3 here

on appeal. The Solosko et al. package 33 contains a separable electrode consisting of

two electrode sections 23 and 25 which are joined by an electrically conductive strip

31. The only connector is connector 39 which is outside the package 33. The

Examiner is trying to read the electrically conductive strip 31 as a connector, but it is

not a connector. this is clear from the paragraph on page 11, lines 24-31 of Solosko et

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al., where connector 39 is referred to as a connector and conductive strip 31 is not; it is referred to as a conductive strip, not a connector. If the Examiner's reasoning were valid, an electrode located in a garage would be "connected" to the street by the driveway and the street would "connect" the driveway to another building on the street, and if the building contained an electrode the two electrodes would be "connected." What is and is not a connector must be determined by how that term is used in the specification. As used in both Solosko et al. and in the present application, a connector is an electrical plug that can be repeatedly plugged into something to attach and removed to detach. The conductive strip 31 is part of a "single separable electrode" which, as Solosko et al. make clear, can only be torn to separate the two sections of the electrode into two electrodes. It is clear from the cited paragraph that Solosko et al. do not consider the strip to be a connector. Consequently both the interior connector and its function are missing from Solosko et al. relative to Claims 2 and 3. Furthermore, it is seen from Fig. 8 of Solosko et al. that their connector 39 is entirely outside of the package 33, with the seam of the package sealed around the electrode wires 35 and 37. This means that leaks can develop in the seam around the wires. By contrast, rewritten Claim 2 says that the defibrillator electrode having a wireset is sealed inside the enclosure, thereby preventing this leakage problem. Accordingly it is respectfully submitted that Solosko et al. cannot anticipate rewritten Claims 2 and 3 and their dependent Claims 4-13.

Claim 14 describes a method for packaging a defibrillator electrode comprising providing a sealable flexible enclosure having an interior connector in the inside of the enclosure and an exterior connector on the outside of the enclosure, the interior and exterior connectors being in electrical communication with each other;

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disposing a defibrillator electrode in the interior of the enclosure, the electrode having an adapter in electrical communication with the interior connector; sealing the enclosure to retard moisture loss; and connecting the exterior connector to be in electrical communication with a defibrillator. The defibrillator electrode sealed in the interior of the disclosure has an adapter connected to the interior connector; no element corresponding to this recited adapter is found Solosko et al. As previously mentioned, there is no interior connector found in Solosko et al. The only connector 39 is outside the package. There is also no adapter inside the package in Solosko et al. For both of these reasons, it is respectfully submitted that Claim 14 and its dependent Claims 15 and 16 cannot be anticipated by Solosko et al.

# B. Rejection of Claims 5-8 and 15-16 as unpatentable over Solosko et al. in view of US Pat. 5,462,157 (Freeman et al.)

Claims 5-8, and 15-16 were rejected under 35 U.S.C. §103(a) as unpatentable over Solosko et al. in view of US Pat. 5,462,157 (Freeman et al.). Freeman et al. have only a single connector 24 or 134, and this single connector is either sealed entirely in the package 10 as shown in Fig. 1 of Freeman et al. or sealed in a seam of the package 100 as shown in Fig. 5 of Freeman et al. Like Solosko et al., only a single connector is present and nothing can be found corresponding to both an interior connector and an exterior connector as recited for the claimed invention. The versatility described above in the explanation of Claim 2 and the different ways in which the electrode and enclosure package connectors can be connected to different defibrillators, is not possible with Freeman et al., as is the case with Solosko et al. For these reasons the combination of Solosko et al. and Freeman et al. cannot render Claims 2 and 3 or Claim 14 and their dependent claims unpatentable. It is respectfully submitted that

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Claims 5-8 and 15-16 are patentable over the combination of Solosko et al. and

Freeman et al. by reason of their dependency.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 2-4 and

9-14 are not anticipated by Solosko et al. and that Claims 5-8 and 15-16 are patentable

over the combination of the Solosko et al. and Freeman et al. patents. Accordingly, it

is respectfully requested that this Honorable Board reverse the grounds of rejection of

these claims stated in the July 16, 2007 Office action being appealed.

Respectfully submitted,

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#### **APPENDIX A: CLAIMS APPENDIX**

The following Claims 2-16 are the claims involved in the appeal.

2. (previously presented) An enclosure for a defibrillator electrode which seals the electrode against moisture loss while the electrode remains in electrical communication with a defibrillator comprising:

an enclosure formed of flexible material which is adapted to be sealed against moisture loss;

an interior connector located on the interior of the enclosure and adapted to detachably connect to a defibrillator electrode; and

an exterior connector located on the outside of the enclosure and adapted to detachably connect to a defibrillator, the exterior connector being in electrical communication with the interior connector, and further comprising:

a defibrillator electrode having a wireset detachably coupled to the interior connector,

wherein the defibrillator electrode is sealed inside of the enclosure.

3. (previously presented) An enclosure for a defibrillator electrode which seals the electrode against moisture loss while the electrode remains in electrical communication with a defibrillator comprising:

an enclosure formed of flexible material which is adapted to be sealed against moisture loss;

an interior connector located on the interior of the enclosure and adapted to detachably connect to a defibrillator electrode; and

an exterior connector located on the outside of the enclosure and adapted to detachably connect to a defibrillator, the exterior connector being in electrical communication with the interior connector, and further comprising:

a defibrillator electrode having a wireset detachably coupled to the interior connector; and

a defibrillator coupled in electrical communication with the exterior connector.

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4. (previously presented) The enclosure of Claim 2, wherein the

enclosure has a wall of flexible material,

wherein the interior and exterior connectors are sealed through a hole in the

wall of flexible material.

5. (previously presented) The enclosure of Claim 4, further comprising a

flange having the interior and exterior connectors located on opposite sides thereof,

wherein the flange is sealed to a hole in the wall of flexible material.

6. (previously presented) The enclosure of Claim 4, further comprising a

flange having the interior and exterior connectors located on opposite sides thereof,

wherein the flange is heat-sealed to the periphery of a hole in the wall of

flexible material.

7. (original) The enclosure of Claim 5, wherein the flange is formed of a

rigid insulative material.

8. (original) The enclosure of Claim 5, wherein the flange is formed of a

rigid insulative, heat-sealable material.

9. (previously presented) The enclosure of Claim 2, wherein the electrode

is detachably connected to the interior connector, the interior connector is in electrical

communication with the exterior connector, and the exterior connector is detachably

connected to the signal path of a defibrillator,

wherein the medical instrument is adapted to monitor the functioning of the

electrode via the signal path.

10. (previously presented) The enclosure of Claim 3, wherein the

defibrillator comprises an external defibrillator.

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11. (previously presented) The enclosure of Claim 2, wherein the enclosure of flexible material comprises a hermetically sealable pouch for storing the electrode.

- 12. (previously presented) The enclosure of Claim 2, wherein the interior connector and the exterior connector comprise an electrical connector having the first end disposed in the interior of the enclosure, and a second end disposed on the exterior of the enclosure.
- 13. (previously presented) The enclosure of Claim 3, wherein the defibrillator further comprises an electrical plug adapted to connect to the exterior connector.
- 14. (previously presented) A method for packaging a defibrillator electrode, comprising:

providing a sealable flexible enclosure having an interior connector in the inside of the enclosure and an exterior connector on the outside of the enclosure, the interior and exterior connectors being in electrical communication with each other;

disposing a defibrillator electrode in the interior of the enclosure, the electrode having an adapter in electrical communication with the interior connector;

sealing the enclosure to retard moisture loss; and

connecting the exterior connector to be in electrical communication with a defibrillator.

- 15. (original) The method of Claim 14, wherein sealing the enclosure comprises heat-sealing the enclosure.
- 16. (previously presented) The method of Claim 14, wherein providing a flexible enclosure further comprises sealing a rigid insulator in a hole in a wall of the enclosure,

wherein the interior and exterior connectors are disposed on opposite sides of the insulator and in electrical communication therethrough.

# **APPENDIX B: EVIDENCE APPENDIX**

None. No extrinsic evidence has been submitted in this case.

# **APPENDIX C: RELATED PROCEEDINGS**

None. There are no related proceedings.